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(54) Bioabsorbable implantable stent with reservoir and process for fabricating the same

Mit einem Reservoir ausgestattete biologisch abbaubare Endoprothese und Verfahren zu ihrer Herstellung

Endprothèse implantable bioabsorbable avec réservoir et méthode de fabrication

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(56) References cited:
EP-A- 0 689 807
WO-A-91/17789
WO-A-93/15787
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Description

Background of the invention

[0001] This invention relates generally to a bioabsorbable implantable stent having one or more reservoir portions, which may include hollow, cavity or porous portions to accumulate by-products of degradation, and to a process for fabricating such a stent.

[0002] Self-expanding medical prostheses frequently referred to as stents are well known and commercially available. They are, for example, disclosed generally in the Wallsten U.S. Patent 4,655,771, and the Wallsten et al. U.S. Patent 5,061,275 and in Hachtmann et al., U.S. Patent No. 5,645,559. Devices are used within body vessels of humans for a variety of medical applications. Examples include intravascular stents for treating stenoses, stents for maintaining openings in the urinary, biliary, tracheobronchial, esophageal, and renal tracts, and vena cava filters.

[0003] A biodegradable drug-delivery vascular stent is described in U.S. Patent 5,500,013, issued on 19th March 1996. This stent in a first embodiment thereof comprises a cylindrical main body, which is surrounded by concentrically arranged fibres. The main body and fibres can be formed of biodegradable materials. In alternative versions, the fibres are hollow, or braided. The fibres are secured to the main body. The main body includes a film that is preferably combined with the fibres by solvation sealing, solvent sealing or heat sealing. A slot runs longitudinally along the body to permit radial compression of the main body and fibres. The fibres provide a spring force that acts radially outward to increase the effective diameter of the main body in the absence of any external radially compressive forces. In a second embodiment a wide strip of biodegradable materal is formed into a coil. The strip has an exterior surface, which can be textured to provide pores, if desired, and a cambered interior surface.

[0004] A delivery device which retains the stent in its compressed state is used to deliver the stent to a treatment site through vessels in the body. The flexible nature and reduced radius of the compressed stent enables it to be delivered through relatively small and curved vessels. In percutaneous transluminal angioplasty, an implantable endoprosthesis introduced through a small percutaneous puncture site, airway, or port and is passed through various body vessels to the treatment site. After the stent is positioned at the treatment site, the delivery device is actuated to release the stent, thereby allowing the stent to self-expand within the body vessel. The delivery device is then detached from the stent and removed from the patient. The stent remains in the vessel at the treatment site as an implant.

[0005] Stents must exhibit a relatively high degree of biocompatibility since they are implanted in the body. An endoprosthesis may be delivered into a body lumen on or within a surgical delivery system such as preferred delivery devices shown in U.S. Patent Nos. 4,954,126 and 5,026,377. Suitable materials for use in such delivery devices are described in U.S. Patent no. 6,042,578. The stents of the present invention may be delivered by alternative methods or by using alternative devices.

[0006] Commonly used materials for known stent filaments include Elgiloy® and Phynox® metal spring alloys. Other metallic materials than can be used for self-expanding stent filaments are 316 stainless steel, MP35N alloy, and superelastic Nitinol nickel-titanium. Another self-expanding stent, available from Schneider (USA) Inc. of Minneapolis, Minnesota, has a radiopaque clad composite structure such as shown in U.S. Patent No. 5,630,840 to Mayer. Self-expanding stents can be made of a Titanium Alloy as described in United States Patent No. 5,888,201.

[0007] The strength and modulus of elasticity of the filaments forming the stents are also important characteristics. Elgiloy®, Phynox®, MP35N and stainless steel are all high strength and high modulus metals. Nitinol has relatively lower strength and modulus.

[0008] The implantation of an intraluminal stent will preferably cause a generally reduced amount of acute and chronic trauma to the luminal wall while performing its function. A stent that applies a gentle radial force against the wall and that is compliant and flexible with lumen movements is preferred for use in diseased, weakened, or brittle lumens. The stent will preferably be capable of withstanding radially occlusive pressure from tumors, plaque, and luminal recoil and remodeling.

[0009] There remains a continuing need for self-expanding stents with particular characteristics for use in various medical indications. Stents are needed for implantation in an ever growing list of vessels in the body. Different physiological environments are encountered and it is recognized that there is no universally acceptable set of stent characteristics. The strength and modulus of elasticity of the filaments forming the stents are important characteristics.

[0010] A need exists for a stent which has self expanding characteristics, but which is bioabsorbable. A surgical implant such as a stent endoprosthesis must be made of a non-toxic, biocompatible material in order to minimize the foreign-body response of the host tissue. The implant must also have sufficient structural strength, biostability, size, and durability to withstand the conditions and confinement in a body lumen.

[0011] A bioabsorbable stent according to the preamble of claim 1 of the present invention is known from document WO 91/17789.

Summary of the Invention

[0012] The present invention is an improved implantable medical device comprised of a tubular, radially compressible, axially flexible and radially self-expandable structure including elongate filaments having reservoir portion. The filaments are formed in a braid-like configuration. The filaments consist of a bioabsorbable polymer which exhibits a relatively high degree of biocompatibility.

[0013] Briefly, self-expanding stents of the present invention are formed from a number of resilient filaments which are helically wound and interwoven in a braided configuration. The stents assume a substantially tubular form in their unloaded or expanded state when they are not subjected to external forces. When subjected to inwardly directed radial forces the stents are forced into a reduced-radius and extended-length loaded or compressed state. The stents are generally characterized by a longitudinal shortening upon radial expansion.

[0014] In one preferred embodiment, the device is a stent which substantially consists of a plurality of elongate poly-lactide bioabsorbable polymer filaments, helically wound and interwoven in a braided configuration to form a tube.

[0015] There is a need for a bioabsorbable implantable endoprosthesis that has a high rate of degradation and may be tailored to degrade over predetermined periods of time. One way to avoid long-term complications from an implant is to make the implant bioabsorbable so that the device is naturally eliminated from the treatment site after it has served its intended function.

[0016] Such a bioabsorbable implantable endoprosthesis would be especially advantageous for medical procedures requiring an endoprosthesis for short term or temporary use. For example, it would be advantageous to implant an implantable endoprosthesis that functions for a specific period of time and does not require a surgical procedure for removal at the end of its functional lifetime. With such an endoprosthesis, there is no need to remove the endoprosthesis because the bioabsorbable material therein decomposes over a period of time into non-toxic biological substances (e.g. lactic acid and glycolic acid) which are easily metabolized or excreted by the body. Such a bioabsorbable implantable endoprosthesis would be advantageous in urological, biliary, vascular, and airway applications where use is desired for only weeks, months, or a few years while a benign stricture is cured or healed, or for use in pre-operative palliation. Such a device may also offer an advantage in that shorter resorption times may reduce the time of inflammatory response and may reduce scarring.

[0017] Bioabsorbable implantable endoprostheses of the present invention include stents which may be made of poly (alpha-hydroxy acid) such as polylactide [poly-L-lactide (PLLA), poly-D-lactide (PDLA)], polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate; polylactic acid-polyethylene oxide copolymers, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials, each of which have a characteristic degradation rate in the body. For example, PGA and polydioxanone are relatively fast-bioabsorbing materials (weeks to months) and PLA and polycaprolactone are relatively slow-bioabsorbing material (months to years).

[0018] An implantable endoprosthesis constructed of a bioabsorbable polymer provides certain advantages relative to metal stents such as natural decomposition into non-toxic chemical species over a period of time. Also, bioabsorbable polymeric stents may be manufactured at relatively low manufacturing costs since vacuum heat treatment and chemical cleaning commonly used in metal stent manufacturing are not required.

[0019] An implantable endoprosthesis made of substantially solid elongate members consisting of PLA generally will require 1-3 years to absorb in a body. However, an implantable endoprosthesis made of PLA, having comparatively shorter resorption times than 1-3 years is desirable for certain indications such as pediatric endoluminal interventions where anatomical growth rates are high and implant size revisions are often necessary. The endoprosthesis of the present invention would be advantageous because the endoprosthesis would absorb over a relatively shorter time and removal thereof would be unnecessary. As the child grows, the appropriate size implantable endoprosthesis could be placed in the body when needed. The resorption time for an implantable endoprosthesis made of a poly (alpha-hydroxy acid) polymer having elongate members including hollow, cavity, or porous portions may be reduced to several days or a few weeks for PGA or to several months to years for PLA.

[0020] The period of time that a bioabsorbable implantable endoprosthesis is functional is dependent upon the degradation rate of the bioabsorbable material and the environment into which it is implanted. The degradation rate of a bioabsorbable endoprosthesis is dependent on chemical composition, processing methods, dimensions, sterilization methods, and geometry of the reservoir portions (i.e. hollow, cavity, or porous portions) of the present invention.

[0021] Bioabsorbable polymer stents are radiolucent and the mechanical properties of the polymers are generally lower than structural metal alloys. Bioabsorbable stents may require radiopaque markers and may have a larger profile on a delivery catheter and in a body lumen to compensate for the lower material properties.

[0022] Bioabsorbable PLLA and PGA material are degraded *in vivo* through hydrolytic chain scission to lactic acid and glycolic acid, respectively, which in turn is converted to CO_2 and then eliminated from the body by respiration. Heterogeneous degradation of semicrystalline polymers occurs due to the fact that such materials have amorphous and crystalline regions. Degradation occurs more rapidly at amorphous regions than at crystalline regions. This results in the product decreasing in strength faster than it decreases in mass. Totally amorphous, cross-linked polyesters show

a more linear decrease in strength with mass over time as compared to a material with crystalline and amorphous regions. Degradation time may be affected by variations in chemical composition and polymer chain structures, and material processing.

[0023] PLA monofilaments may be produced by a process involving seven general steps as summarized herein. First, a polymer formed of poly-L-lactic acid is brought to an elevated temperature above the melting point, preferably 210°-230°C. Second, the material is then extruded at the elevated temperature into a continuous fiber, by a conventional process, at a rate of from about three to four feet per minute. Third, the continuous fiber is then cooled to cause nucleation. The cooling is preferably performed by passing the fiber through a nucleation bath of water. Fourth, the material then passes through a first puller, which runs at about the same speed as the extruder, and places the material under slight tension. Fifth, the fiber is then heated to a temperature between about 60°C and about 90°C (preferably 70°C) as it passes through a heated oven. To perform annealing, the oven can be designed to be quite long and heated near the end, so that the orientation and annealing take place in the same oven. Alternatively, a separate oven can be placed directly after the orientation oven. The annealing step heats the fibers to a range of about 65°C to about 90°C, preferably closer to 90°C. Sixth, while being heated in the orientation oven and the annealing oven, the fiber is drawn between the first puller located before the orientation oven and a second puller located after the annealing oven (if a separate oven). The material is drawn at a draw ratio of between about 5 to about 9, preferably between about 6 and about 8. Draw ratio describes either the reduction in diameter or the extension in length resulting from polymer extrusion or drawing. Quantitatively, the drawing ratio is a unitless value equal to the extruded or drawn length divided by the original length. Maintaining tension through the annealing step prevents shrinkage in later use. The second puller, located at the exit of the oven, runs at an increased speed necessary to provide the desired draw ratio. As the fiber exits the oven and passes through the second puller the tension is immediately released before the material cools. Seventh, finally, the fiber is collected onto spools of desired lengths.

[0024] Strength of the filaments generally increases with draw ratio and with lower draw temperatures. A draw ratio of between 5 and 9 is preferred. PLA is generally amorphous because of the material's slow crystallization kinetics. Very slow cooling after drawing of the filament or use of a nucleating agent will cause crystallization. However, the material may be annealed at temperatures above about 60°C to cause crystallization, and generally, the strength decreases slightly and the modulus increases. Annealing is preferably performed after drawing to release residual stresses and to homogenize the surface to center variations in structure. Annealing will preferably be performed at a temperature of between about 60°C and 150°C for a period of time between about 5 and 120 minutes.

[0025] An endoprosthesis with hollow filaments and closed filament ends can be made by braiding individual strands of extruded tubing. The polymer is melt-extruded through a die containing a center mandrel such that the product is a hollow tube strand. The tube strands are collected onto spools and in a separate operation are transferred from the spools to braid bobbins. After braiding the tubular strands the braid is transferred from the braid mandrel to an anneal mandrel and annealed at a temperature between the glass transistion temperature and the melt temperature of the polymer. The annealed stents are slid off of the anneal mandrel and are cut to the desired endoprosthesis length by clipping each strand in the stent with wire cutters. As the cutting surfaces of the wire cutters close upon the strand the polymer is crimped or flowed and the hollow center is thereby closed. The tubular strands are closed at each end of the stent as a result of the strand cutting operation and the hollow portions are thus generally sealed to prevent significant drainage of accumulating polymer degradation products. It is not necessary for the ends of the hollow strands in a stent to always be sealed closed since capillary forces that would draw the degradation products toward any open ends or that would draw in bodily fluids would not act over such long lengths as with a helical interbraided strand in a stent.

[0026] Reference is made to Enhancement of the Mechanical properties of polylactides by solid-state extrusion, W. Weiler and S. Gogolewski, Biomaterials 1996, Vol. 17 No. 5, pp. 529-535; and Deformation Characteristics of a Bioabsorbable Intravascular Stent, Investigative Radiology, Dec. 1992, C. Mauli, Agrawal, Ph.D., P.E., H. G. Clark, Ph.D., pp. 1020-1024.

[0027] Mechanical properties generally increase with increasing molecular weight. For instance, the strength and modulus of PLA generally increase with increasing molecular weight. Degradation time generally decreases with decreasing initial molecular weight (i.e., a stent made of a low molecular weight polymer would be bioabsorbed before a stent made of a high molecular weight polymer). Low molecular weight PLA is generally more susceptible to thermo-oxidative degradation than high molecular weight grades, so an optimum molecular weight range should be selected to balance properties, degradation time, and stability. The molecular weight and mechanical properties of the material generally decrease as degradation progresses. PLA generally has a degradation time greater than 1 year. Ethylene oxide sterilization process (EtO) is a preferred method of sterilization. PLA has a glass transition temperature of about 60°C, so care must be taken not to store products in environments where high temperature exposure greater than 60°C may result in dimensional distortion.

[0028] PLA, PLLA, PDLA and PGA include tensile strengths of from about 276 MPa (40 thousands of pounds per square inch (ksi) to about 827 MPa (120 ksi) ; a tensile strength of 552 MPa (80 ksi) is typical; and a preferred tensile strength of from about 414 MPa (60 ksi) to about 827 MPa (120 ksi). Polydioxanone, polycaprolactone, and polygluconate

include tensile strengths of from about 103 MPa (15 ksi) to about 414 MPa (60 ksi); a tensile strength of about 241 MPa (35 ksi) is typical: and a preferred tensile strength of from about 172 MPa (25 ksi) to about 310 MPa (45 ksi).

[0029] PLA, PLLA, PDLA and PGA include tensile modulus of from about 2,758 MPa (400,000 pounds per square inch (psi) to about 13,790 MPa (2,000,000 psi); a tensile modulus of 900,000 psi (6,206 MPa) is typical; and a preferred tensile modulus of from about 4,827 MPa (700,000 psi) to about 8,274 MPa (1,200,000 psi) Polydioxanone, polycaprolactone, and polygluconate include tensile modulus of from about 1,379 MPa (200,000 psi) to about 4,827 MPa (700,000 psi) a tensile modulus of 3,103 MPa (450,000 psi) is typical; and a preferred tensile modulus of from about 2,414 MPa (350,000 psi) to about 3,792 MPa (550,000 psi).

[0030] PLLA filament has a much lower tensile strength and tensile modulus than, for example, Elgiloy® metal alloy wire which may be used to make braided stents. The tensile strength of PLLA is about 22% of the tensile strength of Elgiloy®. The tensile modulus of PLLA is about 3% of the tensile modulus of Elgiloy®. Stent mechanical properties and self-expansion are directly proportional to tensile modulus of the material. As a result, a PLLA filament braided stent made to the same design as the metal stent has low mechanical properties and would not be functional. The polymeric braided stents should have radial strength similar to metal stents and should have the required mechanical properties capable of bracing open endoluminal strictures.

[0031] The term "substantially degrades" means that the stent has lost at least 50% of its structural strength. It is preferable that the stent lose about 100% of its structural strength. The included angle between interbraided filaments in the axial orientation is termed "braid angle" prior to annealing and is termed "filament crossing angle" after annealing. A braid becomes a stent after annealing.

[0032] Bioabsorbable resins such as PLLA, PDLA, PGA and other biosbsorbable polymers are commercially available from several sources including PURAC Americal Inc., of Lincolnshire, Illinois.

[0033] In sum, the invention in a first aspect thereof relates to a bioabsorbable implantable stent as claimed in claim 1.

[0034] In a second aspect of the invention a process for fabricating a body implantable stent has the steps set forth in claim 21.

[0035] Advantageous embodiments of the stent and variants of the process are contained in the dependent claims.

[0036] Embodiments of the present invention will now be described by way of further example only and with reference to the accompanying drawings, in which:-

Brief Description of the Drawings

[0037]

FIG. 1 is a side view of a elongate element; FIGS. 2a-2f are side views of six elongate elements of the present invention;

FIGS. 3a-3f are cross-sections of the example elongate member in FIG. 1 taken along the line 3-3 illustrating progressive degradation;

FIGS. 4a-4d are cross-sections of the elongate member in FIG. 2a taken along the line 4-4 illustrating progressive degradation;

FIG. 5 is a side view of one embodiment of a braided endoprosthesis of the present invention; and

FIG. 6 is a graph showing a comparison of the loss of mass over time for a PLLA solid rod and a PLLA cavity rod.

Detailed Description of the Invention

[0038] Reference is made to the example shown in FIG. 1 illustrating a substantially solid elongate member **10** made of a bioabsorbable material such as PLLA or PGA.

[0039] FIGS. 3a-3f illustrate cross-sections of a known member **10** taken along the line 3-3 in FIG. 1 and show progressive degradation occurring most rapidly at the center shaded area **12** where the highest rate of degradation occurs *in vivo*. Degradation occurs when the polymer absorbs water and undergoes hydrolytic scission. Although degradation occurs throughout the member **10**, the rate of degradation will generally be higher at a location having the lower pH as acidic environments catalyze degradation. The diffusion distance **d** of the solid member **10** is measured from the surface **14** to the center of the solid filament. As shown in FIGS 3a-3f, the pH level is reduced in the center shaded area **12** of the solid member 10 because the acidic degradation by-products cannot rapidly migrate away from the location. The degradation rate nearer to the surface **14** of member **10** is relatively slower because the pH level at the surface **14** is not substantially changed since acid degradation by-products are more readily flushed or diffused away.

[0040] FIG. 3a represents the cross-section of a known substantially solid filament of an absorbable polymer, such as PLLA. In subsequent FIGS. 3b-3f, *in vivo* degradation is represented by shaded area **12;** the darker shading in the Figures represents filament areas where the most degradation has occurred or where a faster rate of degradation is occurring. In FIG. 3b, the entire cross section is degrading, but the center shaded area **12** has degraded the most

because acidic degradation products have accumulated there. The area of fast degradation progressively grows with time from the center toward the surface of the cross-section as shown in the increasing size of shaded area **12** in FIGS. 3c-3e. Finally, all that is left of structurally intact material of the substantially solid filament is a surface shell as shown in FIG. 3e. Cracks develop in the shell which lead to disintegration into fragments as shown in FIG. 3f.

[0041] In comparison, reference is made to FIGS. 2a-2f showing filaments which advantageously provide accelerated degradation features compared to known materials. The filaments or elongate members have reservoir portions, specifically: elongate member **20** having at least one hollow **22** portion; elongate member **30** having at least one cavity **32** portion; and elongate member **40** having at least one porous **42** portion. The term "reservoir" is referred to as a volume of space internal to the filament where polymer degradation by-products are collected or stored. The reservoir may be both internal and external passages, with the external passages opening through a filament outside wall or end. FIG. 2a illustrates a hollow member with a center core; FIG. 2b illustrates a member having at least one cavity with sealed ends disposed inside the member; FIG. 2c illustrates a member having at least one pore (internal or external porosity, or both); FIG. 2d illustrates a multi-lumen member with a plurality of hollow portions; FIG. 2e illustrates a cross-section of a member having a plurality of internal pores; FIG. 2f illustrates a member having a plurality of surface pores. The external pores may connect with internal pores, cavities or hollow portions. The reservoir portions have a size greater than about 1 micron and having a volume percentage greater than about 10%. Elongate members may have one or more reservoir portions including combinations of hollow **22**, cavity **32,** or porous **42** portions.

[0042] Reference is made to FIG. 4a which represents a member **20** from FIG. 2a having a manufactured hollow axial portion. When degradation begins as shown by the shading in FIG. 4b, the entire solid tubular section begins to deteriorate. In member **20**, the shaded annular ring area **13b**, shows that the center of the material mass degrades faster because of an accumulation of acidic degradation products in that annular shaded area. In addition, degradation products also accumulate in the hollow axial portion and deterioration of the hollow inner surface area **13a** in member **20** is also accelerated. The member **20** generally degrades into a thin outer shell **13d** and an internal ring **13c** as shown in FIG. 4c. Cracks develop in the inner and outer ring which lead to disintegration as shown in FIG. 4d. Degradation and disintegration of member **20** is advantageously faster than the substantially solid member **10** because there are two regions of accelerated degradation, in areas **13a** and **13b.**

[0043] FIGS. 4a-4d illustrate cross-sections taken along the line 4-4 of FIG. 2a and show progressive degradation of the elongate member **20** in areas where the highest rate of degradation occurs *in vivo.* Although degradation occurs throughout the member **20**, the rate of degradation is generally higher at a location having the lower pH as acidic environments catalyze degradation. By-products from degradation such as lactic acid or glycolic acid are stored in the hollow **22,** cavity **32,** or porous **42** portions which act as reservoirs and advantageously accelerate the degradation of the inner surfaces. The diffusion distance $\mathbf{d_1}$ in elongate members **20, 30, 40** is relatively shorter than the diffusion distance **d** in elongate member **10.** The diffusion distance $\mathbf{d_1}$ is measured from the outside surface **14** to the inside surface **14a.** In the present invention, the combination of generally shorter water absorption distance $\mathbf{d_1}$, resulting generally shorter water absorption time, and relatively accelerated degradation at the by-product reservoir areas results in relatively faster overall polymer resorption of the elongate members **20, 30,** and **40** or endoprosthesis **50** *in vivo.* The elongate members **20, 30,** and **40** may further comprise one or more internal or external walls 25 that are adapted to bioabsorb *in vivo.* Tables 1 and 2 below describes preferred reservoir and endoprostheses embodiments.

Table 1

Type of Reservoir:	% Volume Solid	% Volume Hollow or Cavity	Hollow or Cavity Features Dimensions
axial core (one lumen tubing)	65-90	10-35	∅<50% of O.D. x length of filament strand
multi-lumen filament (two or more lumens)	50-90	10-40	∅<50% of O.D./# of lumens, length of filament strand
internal porosity	70-90	10-30	1-20 microns
external porosity (surface oriented)	80-90	10-20	1-20 microns

Table 2

# Of Filament Strands In Braid	Braid Mandrel Diameter, mm	Braid Angle, Degrees	PLLA Diameter, mm	PDLA Diameter, mm	PLLA/PDLA Diameter, mm	PGA Diameter, mm
10	3-6	120-150	.15-.25	.15-.25	.15-.25	.20-.30
10	3-6	120-150	.20-.30	.20-.30	.20-.30	.25-.35
12	3-8	120-150	.20-.30	.20-.30	.20-.30	.25-.35
12	3-8	120-150	.35-.45	.35-.45	.35-.45	.40-.50
15	6-10	120-150	.30-.40	.30-.40	.30-.40	.35-.45
15	6-10	120-150	.35-.45	.35-.45	.35-.45	.40-.50
18	7-12	120-150	.35-.45	.35-.45	.35-.45	.40-.50
18	7-12	120-150	.40-.50	.40-.50	.40-.50	.45-.55
20	3-9	120-150	.20-.30	.20-.30	.20-.30	.25-.35
24	8-12	120-150	.20-.30	.20-.30	.20-.30	.25-.35
24	9-14	120-150	.25-.35	.25-.35	.25-.35	.30-.40
24	12-18	120-150	.30-.40	.30-.40	.30-.40	.35-.45
30	16-26	120-150	.30-.40	.30-.40	.30-.40	.35-.45
36	20-30	120-150	.35-.45	.35-.45	.35-.45	.40-.50
24	14-20	120-150	.35-.45	.35-.45	.35-.45	.40-.50

# Of Filament Strands In Braid	Braid Mandrel Diameter, mm	Braid Angle, Degrees	PGA/ PLLA Diameter, mm	PGA/ Polycaprolactone Diameter, mm	Polydioxanone Diameter, mm	PGA/ trimethylene carbonate Diameter, mm
10	3-6	120-150	.20-.30	22-.32	25-.35	.22-.32
10	3-6	120-150	.25-.35	.27-.37	.30-.40	.27-.37
12	3-8	120-150	.25-.35	.27-.37	.30-.40	.27-.37

(continued)

# Of Filament Strands In Braid	Braid Mandrel Diameter, mm	Braid Angle, Degrees	PGA/ PLLA Diameter, mm	PGA/ Polycaprolactone Diameter, mm	Polydioxanone Diameter, mm	PGA/ trimethylene carbonate Diameter, mm
12	3-8	120-150	.40-.50	.42-.52	.45-.55	.42-.52
15	6-10	120-150	.35-.45	.37-.47	.40-.50	.37-.47
15	6-10	120-150	.40-.50	.42-.52	.45-.55	.42-.52
18	7-12	120-150	.40-.50	.42-.52	.45-.55	.42-.52
18	7-12	120-150	.45-.55	.47-.57	.50-.60	.47-.57
20	3-9	120-150	25-.35	.27-.37	.30-.40	.27-.37
24	8-12	120-150	.25-.35	.27-.37	.30-.40	.27-.37
24	9-14	120-150	.30-.40	.32-.42	.35-.45	.32-.42
24	12-18	120-150	.35-.45	.37-.47	.40-.50	.37-.47
30	16-26	120-150	.35-.45	.37-.47	.40-.50	.37-.47
36	20-30	120-150	.40-.50	.42-.52	.45-.55	.42-.52
24	14-20	120-150	.40-.50	.42-.52	.45-.55	.42-.52

[0044] Reference is made to FIG. 5 illustrating one embodiment of an implantable endoprosthesis **50** comprising elongate members made of a bioabsorbable polymer and having one or more hollow **22**, cavity **32**, or porous **42** portions (hollow, cavity, or porous portions not shown). The hollow **22**, cavity **32**, or porous **42** portions shorten the diffusion distance for water absorption and act as reservoirs to accumulate by-product from the degradation of the bioabsorbable material and thereby relatively increase the degradation rate of the structure. The bioabsorbable implantable endoprosthesis **50** may be elastically or plastically expandable and be made from polyester bioabsorbable polymers including PLA and PGA, as well as other polymers.

[0045] A bioabsorbable implantable prosthesis or stent **50** in accordance with the present invention is illustrated generally in FIG 5. Stent **50** is a tubular device formed from elongated strands or filaments **20, 30, 40.** The filaments **20, 30, 40** are interwoven to form an open mesh or weave construction. As described in greater detail below, at least one and preferably all filaments **20, 30, 40** consists of one or more commercially available grades of poly(alpha-hydroxy acid) such as poly-L-lactide (PLLA), poly-D-lactide (PDLA), polyglycolide (PGA), polydioxanone, polycaprolactone, polygluconate, polylactic acid-polyethylene oxide copolymers, poly(hydroxybutyrate), polyanhydride, polyphosphoester, poly(amino acids), or related copolymers materials. Methods for fabricating stents **50** are generally known and disclosed, for example, in the Wallsten U.S. Patent 4,655,771 and the Wallsten et al. U.S. Patent 5,061,275.

[0046] Stent 50 is shown in its expanded or relaxed state FIG 5 in the configuration it assumes when subject to no external loads or stresses. The filaments **20, 30, 40** are resilient, permitting the radial compression of stent **50** into a reduced-radius, extended-length configuration or state suitable for delivery to the desired placement or treatment site through a body vessel (i.e., transluminally). Stent **50** is also self-expandable from the compressed state, and axially flexible.

[0047] The tubular and self-expandable body or structure formed by the interwoven filaments **20, 30, 40** is a primary prosthetically-functional structure of stent **50**, and for this reason the device can be considered to substantially consist of this structure to the exclusion of other structures. However, it is known that other structures and features can be included in stents, and in particular features which enhance or cooperate with the tubular and self-expandable structure or which facilitate the implantation of the structure. One example is the inclusion of radiopaque markers on the structure which are used to visualize the position of the stent through fluoroscopy during implantation. Another example is the inclusion of a covering or additional interwoven filaments, for instance, to reduce the porosity or open spaces in the structure so that the stent can be used to prevent tissue ingrowth or be used as a graft. Other examples include collapsing threads or other structures to facilitate repositioning and removal of the stent. Stents of these types nonetheless still substantially consist of the tubular and self-expandable structure formed by interwoven filaments **20, 30, 40**.

[0048] In the present invention, the in-vivo absorption time of bioabsorbable implantable endoprosthesis **50** is dependent upon the absorbable polymer used in the device, material processing, and the implant environment (pH, chemical composition of fluids, mechanical loading). Each polymer has its own characteristic degradation rate in the body based on its composition and structure. The degradation rate is also affected by manufacturing, sterilization, storage, geometry, and the specific environment in which the polymer is implanted. For a given set of implant conditions, a specific absorption time may be designed by utilizing fast-absorbing or slow-absorbing polymer.

[0049] Each polymer also has different physical and mechanical properties. For example, PLA has a moderately high modulus and strength and high ductility and PGA has a high modulus and a lower ductility (stiff and relatively brittle). An endoprosthesis 50 may have bioabsorbable polymer elongate elements having a tensile modulus of from about 2,758 MPa (400,000) to about 13,790 MPa (2,000,000 psi) The preferred range of tensile modulus for an endoprosthesis 50 made of bioabsorbable polymer elongate elements is from about 4,827 MPa (700,000) to about 8,274 MPa (1,200,000 psi). A preferred embodiment of the bioabsorbable polymer elongate elements includes about a 6,895 MPa (1,000,000 psi) tensile modulus and about a 621 MPa (90 ksi) tensile strength. For structural elongate members 20, 30, 40 that are loaded primarily in bending or torsion, the maximum von Mises equivalent stresses are at the surface and the stress at the center of the elongate member is zero, so a hollow **22** portion may be used. It may be desirable to have the ductile properties of PLA and the short resorption time of PGA in one implant. One way to achieve this is to use copolymers of PLA and PGA, but this may result in a compromise of characteristics. The present invention allows the device designer to select the polymer based on desirable biocompatibility, and mechanical and physical properties with less concern for the material degradation rate by utilizing the one or more reservoir portion features to tailor the degradation rate beyond the rate that would be expected with a substantially solid material construction.

[0050] Bioabsorbable polymer surgical implants and sutures lose their original tensile strength and mass over a period of time in the environment of the body. The retention time of the original tensile strength is important, because the device or suture must serve its intended structural purpose for a period of time that is long enough to allow healing to occur. Subsequent to healing, the polymer may lose strength since the structural support is now performed by native tissue or bone. The healing time varies depending on the type of tissues involved; skin, tendon, bone, or muscle. A polymer with an appropriate strength retention time must be selected for each type of medical indication.

[0051] The polymer degradation rate is influenced by several intrinsic and extrinsic factors. Intrinsic factors include the chemical composition and physical structure of the polymer (such as substituents, orientation, level of crystallinity,

geometry, and molecular weight). Extrinsic factors include the pH of the biological medium, electrolytes, external stress, temperature, radiation, free radicals, and enzymes.

[0052] The degradation of absorbable polymers is primarily due to hydrolysis. The hydrolytic reaction causes the polymer molecular chains to be broken and the chain length decreases with the duration of degradation. The result of decreasing chain length is a reduction in physical and mechanical properties. Loss of mass occurs when a significant number of chains are broken to allow diffusion of small molecular chains out of the polymer and into the biological environment. Disintegration of the device occurs when there has been loss of strength and mass and portions of the polymer fragment.

[0053] The three types of degradation properties that are used to describe the absorbable polymer degradation process are loss of tensile strength profile, loss of mass profile, and type of degradation products released into the surrounding tissues. The loss of tensile strength always precedes the other two events, because the absorbable polymers degrade by hydrolysis throughout the bulk of the material rather than from surface erosion. Bulk degradation causes the polymer to lose strength first and then to lose mass. If degradation were to occur by surface erosion, the polymer would lose mass before or at the same time as it loses strength.

[0054] All synthetic absorbable sutures are water-insoluble polymers. This means that the rate of diffusion of water is an important factor in determining the rate of hydrolysis and degradation. Thinner sections should theoretically reach the bulk water concentration level where hydrolysis can start to occur faster than thick sections. However, once degradation starts, thicker sections will have faster degradation rates because the acidic degradation products in the center of the section build up and catalyze degradation to a faster rate than in other locations in the material where diffusion distances are shorter and the degradation products migrate to the surface and are buffered by the biological environment. The result is that the degradation profile is at a maximum at the center of the solid section and decreases from the center to the surface. Degradation occurs throughout the bulk, but is faster in the center. In, for example, a hollow section where degradation products can collect in the reservoir, there are two locations of high degradation rate; the surface of the member at the reservoir and the center of the solid section. Therefore, the degradation of a hollow piece should occur sooner than a solid piece because the diffusion distance for water absorption is shorter and because there are two fast-degrading fronts in the material.

[0055] For PLA, structural degradation occurs over a time interval of about 6 months to 2 years in-vivo. A member will disintegrate after it loses enough strength and is no longer capable of withstanding applied loads or is no longer capable of holding itself together. Structural degradation takes place long after the time needed for endothelialization or epithelialization of the device.

[0056] Absorption occurs when polymer degradation products are released from the device and introduced into normal body chemical processes. Metabolism is the chemical changes in living cells by which energy is provided for vital processes and activities and new material is assimilated to repair the waste.

[0057] Excretion is separation and elimination or discharge from the blood or tissues of useless, superfluous, or harmful material that is eliminated from the body. Excretion differs from a secretion in not being produced to perform a useful function.

[0058] The biocompatibility of absorbable polymers during degradation depends upon the rate of accumulation and how well the surrounding tissue or fluid buffers or metabolizes the degradation products. If the products are metabolizable, the rate at which this will occur is dependent upon the blood circulation in the tissue. A well-vascularized lumen wall could buffer and metabolize degradation products as they are released from the implant. This biological process is important to minimize adverse tissue reaction to the degrading implant.

[0059] The final degradation products from PLLA and PGA are lactic and glycolic acid which are normally present in the human body. The acids are metabolized by cells around the implant. The metabolization process is a citrate cycle which converts the acids to carbon dioxide which is respirated out of the body.

[0060] For a PLA member, mass degradation is completed with total absorption of the polymer endoprosthesis in about 1.5 to 3 years after implantation.

[0061] To manufacture the implantable endoprosthesis **50**, the tubular braided filament endoprosthesis **50** is disposed on a stainless steel tubular mandrel (not shown) and held in an axially compressed position, axially extended position, or a free state position with plastic tie-wraps or comparable instruments (not shown) to form an assembly. The term "free state" is used when no externally applied forces are acting on the device, for example, when the device is resting on a table. The assembly is annealed at a temperature less than the melting point of the endoprosthesis **50** for a time of from about 5 minutes to about 90 minutes. The endoprosthesis **50** may be annealed at a temperature of from about 130°C to about 160°C for about 10 minutes to about 20 minutes. A preferable annealing process includes temperature at about 140°C for about 15 minutes in air, vacuum, argon, helium, or combinations thereof. Thereafter, the assembly is cooled to a room temperature, and the endoprosthesis **50** is slid off of the mandrel. The implantable endoprosthesis **50** is then cut to predetermined longitudinal lengths by clipping the entire endoprosthesis **50** or each filament crossing point.

[0062] The hollow **22**, cavity **32**, or porous **42** portions may be made by an extrusion process using mandrels or by coring during injection molding. Porosity may be made by processes including machining, dissolvable microspheres,

extrusion or molding parameter selection, gas bubbling, or like methods.

[0063] Examples of the present invention are described below.

Example 1

[0064] In an experiment, a solid extruded PLLA rod (solid rod) and an extruded PLLA rod having two cavity portions (cavity rod) were used to demonstrate faster absorption of the cavity rod. The solid rod and the cavity rod were made from the same initial solid rod which was first annealed in air at 140°C for about 15 minutes. The solid rod was cut into 15.2 mm-17.8 mm (.6"-.7") lengths.

[0065] The solid rod had a measured outside diameter of about 5.4 mm (0.212") and had a length of about 15.2 mm-17.8 mm (0.6"-0.7"). The cavity rod measured an outside diameter of about 5.4 mm (0.212"), and had a length of about 15.2 mm-17.8 mm (0.6"-0.7"), and included cavities at each end measuring 2 mm (5/64") diameter by 5 mm-7 mm (.2"-.3") deep. The cavity rod was made by using one of the solid PLLA lengths an drilling an axial hole at each end using a 2 mm (5/64") drill a depth of 5 mm-7 mm (.2"-.3"). The cavity opening at the end of each axial hole was covered with medical grade Dow silicone adhesive A, thus creating two internal cavities in the rod to form the cavity rod.

[0066] The solid rod and the cavity rod were put in separate 32 oz. jars filled with a phosphate buffered saline (PBS) solution (pH = 7.4). Each jar was incubated at 60°C. The solid rod and the cavity rod were each inspected for weight change and for evidence of fracture on a regular basis. The weight of the solid rod and the cavity rod included the by products of degradation.

[0067] The solid rod and the cavity rod were weighed prior to the experiment (day 0) and on the following days of the experiment: 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, 17, 18, 19, 20, 21, 22, 25, and 26. The solid rod and the cavity rod were not weighed on the following days of the experiment: 1, 2, 8, 9, 15, and 16.

[0068] The results of the experiment showed that both the solid rod and the cavity rod gained weight for the first 10 days (presumably from water absorption); and that the cavity rod gained weight faster than the solid rod. The solid rod and the cavity rod began losing weight after 10 days of incubation (presumably from polymer degradation). The cavity rod fractured at 22 days of incubation with about 0.6% loss of its original specimen weight as compared to the solid rod which fractured at 26 days of incubation with about 1.3% loss of its original specimen weight. Testing and measurements were completed when fracture of each respective rod occurred.

[0069] Bioabsorbable member or device fracture (disintegration) is an important milestone in the process of bioabsorption because it marks the certain end to the functional usefulness of the member or device in the body. At the point of disintegration, the member or device can no longer provide luminal support and degrades away in the body. Disintegration is a useful measure of degradation time because it is easy to measure through observation and compared.

[0070] Table 3 shows measurements recorded during the experiment in tabular form. Figure 6 illustrates the results of the experiment from Table 3 in graphical form.

Table 3

Days	Cavity Rod, g	Solid Rod, g	% Loss Of Mass, (Cavity)	% Loss Of Mass, (Solid)
0	0.4211	0.5005	0	0
1	no measurement	no measurement		
2	no measurement	no measurement		
3	0.4211	0.5005	0	0
4	0.4227	0.5023	-0.4	-0.4
5	0.4245	0.5044	-0.8	-0.8
6	0.4268	0.5061	-1.4	-1.1
7	0.4295	0.5081	-2	-1.5
8	no measurement	no measurement		
9	no measurement	no measurement		
10	0.4408	0.5178	-4.7	-3.5
11	0.4351	0.5145	-3.3	-2.8
12	0.4326	0.5123	-2.7	-2.4
13	0.432	0.5108	-2.6	-2.1

(continued)

Days	Cavity Rod, g	Solid Rod, g	% Loss Of Mass, (Cavity)	% Loss Of Mass, (Solid)
14	0.4296	0.5082	-2	-1.5
15	no measurement	no measurement		
16	no measurement	no measurement		
17	0.4262	0.5041	-1.2	-0.7
18	0.4244	0.503	-0.8	-0.5
19	0.4248	0.5027	-0.9	-0.4
20	0.424	0.5025	-0.7	-0.4
21	0.4236	0.5025	-0.6	-0.4
22	0.4184	0.4979	0.6	0.5
25		0.4944		1.2
26		0.4938		1.3

[0071] In sum, the cavity rod fractured in less time than the solid rod. The cavity rod fractured in 22 days as compared to the solid rod which fractured in 26 days. Also, the cavity rod required less mass degradation prior to fracture than the solid rod. The experiment demonstrated that a PLLA bioabsorbable member having two cavities would degrade faster than a solid member. The faster degradation was found to result from a shorter diffusion distance across the section thickness and from acceleration of degradation on the inner surface of the cavity from collection of acidic degradation products. The absorption time for the cavity rod could be made to be longer or shorter by changing the volume percentage of the cavity areas or changing the geometry of the reservoir area (i.e. round, elongate, small or large). Furthermore, the degradation rate of bioabsorbable implantable endoprostheses may be manipulated without changing materials or processing methods.

Example 2

[0072] Stents **50** can be fabricated from 10 filament strands of 0.15-0.25 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.20-0.30 mm diameter PGA, PGA-PLLA copolymer, 0.22-0.32 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylene carbonate copolymer, or 0.25-0.35 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to about twenty microns. The filaments are disposed on a 3-6 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel, and cut to the desired stent length.

Example 3

[0073] Stents **50** can be fabricated from 10 filament strands of 0.20-0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25-0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27-0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30-0.40 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to about twenty microns. The filaments are disposed on a 3-6 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the

anneal mandrel, and cut to the desired stent length.

Example 4

[0074] Stents 50 can be fabricated from 12 filament strands of 0.20-0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25-0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27-0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30-0.40 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 3-8 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 5

[0075] Stents **50** can be fabricated from 12 filament strands of 0.35-0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40-0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42-0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45-0.55 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 3-8 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 6

[0076] Stents 50 can be fabricated from 15 filament strands of 0.30-0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35-0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37-0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40-0.50 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 6-10 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 7

[0077] Stents **50** can be fabricated from 15 filament strands of 0.35-0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40-0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42-0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45-0.55 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 6-10 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the

polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 8

[0078] Stents **50** can be fabricated from 18 filament strands of 0.35-0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40-0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42-0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45-0.55 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 7-12 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 9

[0079] Stents 50 can be fabricated from 18 filament strands of 0.40-0.50 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.45-0.55 mm diameter PGA, PGA-PLLA copolymer, 0.47-0.57 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.50-0.60 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 7-12 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 10

[0080] Stents **50** can be fabricated from 20 filament strands of 0.20-0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25-0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27-0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30-0.40 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 3-9 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 11

[0081] Stents **50** can be fabricated from 24 filament strands of 0.20-0.30 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.25-0.35 mm diameter PGA, PGA-PLLA copolymer, 0.27-0.37 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.30-0.40 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 8-12 mm diameter braid mandrel

with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 12

[0082] Stents **50** can be fabricated from 24 filament strands of 0.25-0.35 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.30-0.40 mm diameter PGA, PGA-PLLA copolymer, 0.32-0.42 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.35-0.45 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 9-14 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 13

[0083] Stents **50** can be fabricated from 24 filament strands of 0.30-0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35-0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37-0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40-0.50 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 12-18 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 14

[0084] Stents **50** can be fabricated from 30 filament strands of 0.30-0.40 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.35-0.45 mm diameter PGA, PGA-PLLA copolymer, 0.37-0.47 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.40-0.50 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 16-26 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 15

[0085] Stents **50** can be fabricated from 36 filament strands of 0.35-0.45 mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40-0.50 mm diameter PGA, PGA-PLLA copolymer, 0.42-0.52 mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45-0.55 mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with

diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 20-30 mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10 mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free, or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

Example 16

[0086] Stents 50 can be fabricated from 24 filament strands of 0.35-0.45mm diameter PLLA, PDLA, PLLA-PDLA copolymer, 0.40-0.50mm diameter PGA, PGA-PLLA copolymer, 0.42-0.52mm diameter PGA-polycaprolactone copolymer, PGA-trimethylcarbonate copolymer, or 0.45-0.55mm diameter polydioxanone. The filaments with reservoirs in the form of hollow cores with diameters less than about 50% of the filament outer diameter extending over the entire filament length (except for sealed ends at the end of each filament that may occur during manufacturing); cavities with diameters less than about 50% of the filament outer diameter extending over one or portions of the entire filament length; or pores with diameters of about one to twenty microns. The filaments are disposed on a 14-20mm diameter braid mandrel with a filament braid angle of 120-150 degrees while the braid is on the braid mandrel and annealed on a bar or tube mandrel that has an outer diameter 0.2-10mm smaller than the braid mandrel diameter at a temperature between the polymer glass-transition temperature and the melting temperature for 5-120 minutes in air, vacuum, or inert atmosphere with the braid in an axially extended, free or contracted position, cooled to about room temperature, slid off the anneal mandrel and cut to the desired stent length.

[0087] It will be evident from considerations of the foregoing that the bioabsorbable implantable endoprosthesis may be constructed using a number of methods and materials, in a wide variety of sizes and styles for the greater efficiency and convenience of a user.

[0088] A bioabsorbable stent that may advantageously be used in conjunction with the present invention is disclosed in J Stinson's United States Patent No. 6,245,103 entitled "Bioabsorbable Self-Expanding Stent" based on application No. 08/904,467, filed concurrently herewith, and commonly assigned to the assignee of this application.

[0089] A bioabsorbable marker that may advantageously be used in conjuction with the present invention is disclosed in J Stinson's and Claude Clerc's United States Patent No. 6,340,367 entitled "Radiopaque Markers and Methods of Using Same", based on application No. 08/905,821, filed concurrently herewith, and commonly assigned to the assignee of this application.

[0090] Another bioabsorbable marker that may advantageously be used in conjunction with the present invention is disclosed in J Stinson's United States Patent No. 6,174,330 entitled "Bioabsorbable Marker having Radiopaque Constituents and Method of Using the Same", based on application No. 08/904,951, filed concurrently herewith, and commonly assigned to the assignee of this application.

[0091] The above described embodiments of the invention are merely descriptive of its principles and are not to be considered limiting. The scope of the invention is defined by the following claims.

Claims

1. A bioabsorbable implantable stent, including:

   a radially compressible and self-expandable braided and annealed tubular structure (50) comprising a first set of elongate members (20, 30, 40) extending in a helix configuration in a first direction of winding along a centerline of the tubular structure, and a second set of elongate members (20, 3 0, 40) extending in a helix configuration in a second direction of winding along the centerline and crossing the first set of elongate members to form crossings of the elongate members and interstices between the elongate members;

   wherein each of the elongate members includes a bioabsorbable polymer adapted to undergo degradation *in vivo*; and wherein the elongate members are resilient to permit radial compression of the tubular structure into a reduced-radius, extended-length state to facilitate a transluminal delivery of the tubular structure to a selected treatment site, **characterised in that** each of said elongate members further includes a reservoir portion adapted to collect a byproduct of the degradation of the bioabsorbable polymer, with the reservoir portion occupying a reservoir volume greater than about five percent of a total volume occupied by the elongate member.

2. The stent of claim 1 wherein:

the reservoir portion comprises a hollow portion extending axially along each of the elongate members and open to opposite ends of each element.

3. The stent of claim 2 wherein:

the reservoir portion comprises a plurality of said hollow portions.

4. The stent of claim 2 wherein:

an average cross-sectional area of the hollow portion comprises from about ten percent to about 30 percent of the total elongate member cross-sectional area.

5. The stent of claim 1 wherein:

the reservoir portion comprises at least one axially extending internal cavity recessed from the outer surface of each of the elongate members.

6. The stent of claim 5 wherein:

the at least one cavity has an average cross-sectional area ranging from about two percent to about 40 percent of the total elongate member cross-sectional area.

7. The stent of claim 5 wherein:

an average cross-sectional area of the cavity ranges from about ten percent to about 30 percent of a cross-sectional area of its associated elongate member.

8. The stent of claim 1 wherein:

the reservoir portion comprises a plurality of pores.

9. The stent of claim 8 wherein:

the pores are recessed from an outer surface of each of the elongate members.

10. The stent of claim 8 wherein:

at least some of the pores of each elongate member are open to an outer surface of the elongate member.

11. The stent of claim 10 wherein:

substantially all of the pores of each elongate member are open to the outer surface of the elongate member.

12. The stent of claim 1.0 wherein:

the outer surface of each of the elongate members has a total outer surface area that includes a pore surface area consisting of the combined surface areas of the pores open to the outer surface; and
the total pore surface area ranges from about two percent to about forty percent of the total outer surface area.

13. The stent of claim 8 wherein:

the pores have diameters ranging from about 1 micron to about 20 microns.

14. The stent of claim 1 wherein:

the volume of each reservoir portion ranges from twenty percent to about forty percent of its associated total volume.

15. The stent of claim 14 wherein:

the elongate members, at the multiple crossings, form crossing angles ranging from about 120 degrees to about 150 degrees.

16. The stent of claim 1 wherein:

the bioabsorbable polymer consists essentially of a polymer selected from the group consisting of: PLLA, PDLA, and their combinations.

17. The stent of claim 1 wherein:

the bioabsorbable polymer consists essentially of a polymer selected from the group consisting of: polylactide, polyglycolide, and their combinations.

18. The stent of claim 1 wherein:

the bioabsorbable polymer consists of a polymer selected from the group consisting of: polyglycolide, polygluconate, polydioxanone, and their combinations.

19. The stent of claim 1 wherein:

each of the elongate members consists essentially of the bioabsorbable polymer.

20. The stent of claim 1 wherein:

the elongate members are resilient, whereby the tubular structure tends to assume a free state in which the tubular structure has a first diameter, and when radially compressed into the reduced-radius extended-length state has a second diameter less than the first diameter.

21. A process for fabricating a body implantable stent comprising first and second sets of resilient elongate members, including:

providing a tubular structure (50) including a first set of elongate members (20, 30, 40) extending in a helix configuration in a first direction of winding along a centerline of the tubular structure, and a second set of elongate members (20, 30, 40) extending in a helix configuration along the centerline in a second direction of winding and crossing the first set of elongate members to form crossings of the elongate members and interstices between the elongate members, wherein the tubular structure is radially compressible into a reduced-radius, extended-length state, and wherein each of the elongate members includes a bioabsorbable polymer adapted to undergo degradation *in vivo* and further includes a reservoir portion adapted to collect a byproduct of the degradation of the biodegradable polymer, with the reservoir portion occupying a reservoir volume greater than about five percent of a total elongate member volume occupied by the elongate member,
disposing the tubular structure on a mandrel, and with the tubular structure disposed on the mandrel, annealing the tubular structure at a temperature less than the melting point of the bioabsorbable polymer for a time of from 5 minutes to 120 minutes; and
after annealing, cooling the tubular structure, then removing the tubular structure from the mandrel.

22. The process of claim 21 wherein:

said providing a tubular structure comprises forming the respective reservoir portions in the elongate members.

23. The process of claim 22 wherein:

said forming the respective reservoir portions includes extruding the elongate members in a manner to provide the respective reservoir portions.

24. The process of claim 22 wherein:

said forming the reservoir portions includes coring the elongate members during an injection molding thereof.

25. The process of claim 22 wherein:

said forming the reservoir portions comprises incorporating dissolvable microspheres into the elongate members.

26. The process of claim 22 wherein:

said forming the reservoir portions comprises drilling axial holes in the elongate members.

27. The process of claim 26 wherein:

said providing the reservoir portions further includes sealing respective open ends of the axial holes in the elongate members.

28. The process of claim 21 further including:

after removing the tubular structure from the mandrel, cutting the tubular structure into predetermined axial lengths.

29. The process of claim 21 wherein:

said annealing comprises heating the tubular structure to a temperature within a range from about 130 degrees C to about 160 degrees C, for a time within a range from about ten minutes to about twenty minutes.

30. The process of claim 21 wherein:

said providing the tubular structure comprises braiding the elongate members on a braiding mandrel to determine a pre-annealing diameter of the tubular structure when in a free state.

31. The process of claim 30 wherein:

said annealing comprises maintaining the tubular structure in the free state on the annealing mandrel.

32. The process of claim 30 wherein:

said annealing comprises maintaining the tubular structure in an axially extended state on the annealing mandrel.

33. The process of claim 30 wherein:

said annealing comprises maintaining the tubular structure in an axially compressed state on the annealing mandrel.

Patentansprüche

1. Biologisch abbaubare, implantierbare Endoprothese, umfassend:

eine radial zusammendrückbare und selbstdehnbare, geflochtene und getemperte Röhrenstruktur (50), umfassend einen ersten Satz von länglichen Elementen (20, 30, 40), die sich in einer spiralförmigen Anordnung in einer ersten Wickelrichtung entlang einer Mittellinie der Röhrenstruktur erstrecken, und einen zweiten Satz von länglichen Elementen (20, 30, 40), die sich in einer spiralförmigen Anordnung in einer zweiten Wickelrichtung entlang der Mittellinie erstrecken und mit dem ersten Satz von länglichen Elementen kreuzen, um Kreuzungen der länglichen Elemente und Zwischenräume zwischen den länglichen Elementen zu bilden;

wobei jedes der länglichen Elemente ein biologisch abbaubares Polymer umfasst, das so ausgelegt ist, dass es eine in-vivo-Zersetzung erfährt, und
wobei die länglichen Elemente elastisch sind, um ein radiales Zusammendrücken der Röhrenstruktur in einen

Zustand mit verkleinertem Radius und erweiterter Länge zu ermöglichen, um eine transluminale Zuführung der Röhrenstruktur zu einer ausgewählten Behandlungsstelle zu erleichtern, **dadurch gekennzeichnet, dass** jedes der länglichen Elemente ferner einen Reservoirabschnitt umfasst, der so ausgelegt ist, dass er ein Nebenprodukt der Zersetzung des biologisch abbaubaren Polymers sammelt, wobei der Reservoirabschnitt ein Reservoirvolumen einnimmt, das größer als etwa fünf Prozent eines Gesamtvolumens ist, das durch das längliche Element eingenommen wird.

2. Endoprothese nach Anspruch 1, wobei:

der Reservoirabschnitt einen Hohlraumabschnitt umfasst, der sich axial entlang jedes der länglichen Elemente erstreckt und zu gegenüberliegenden Enden jedes Elements offen ist.

3. Endoprothese nach Anspruch 2, wobei:

der Reservoirabschnitt eine Mehrzahl der Hohlraumabschnitte umfasst.

4. Endoprothese nach Anspruch 2, wobei:

eine mittlere Querschnittsfläche des Hohlraumabschnitts von etwa zehn Prozent bis etwa 30 Prozent der Gesamtquerschnittsfläche des länglichen Elements umfasst.

5. Endoprothese nach Anspruch 1, wobei:

der Reservoirabschnitt wenigstens eine sich axial erstreckende innere Höhlung umfasst, die von der Außenfläche jedes der länglichen Elemente vertieft ist.

6. Endoprothese nach Anspruch 5, wobei:

die wenigstens eine Höhlung eine mittlere Querschnittsfläche aufweist, die von etwa zwei Prozent bis etwa 40 Prozent der Gesamtquerschnittsfläche des länglichen Elements reicht.

7. Endoprothese nach Anspruch 5, wobei:

eine mittlere Querschnittsfläche der Höhlung von etwa zehn Prozent bis etwa 30 Prozent einer Querschnittsfläche ihres zugehörigen länglichen Elements reicht.

8. Endoprothese nach Anspruch 1, wobei:

der Reservoirabschnitt eine Mehrzahl von Poren umfasst.

9. Endoprothese nach Anspruch 8, wobei:

die Poren von einer Außenfläche jedes der länglichen Elemente vertieft sind.

10. Endoprothese nach Anspruch 8, wobei:

wenigstens einige der Poren jedes länglichen Elements zu einer Außenfläche des länglichen Elements offen sind.

11. Endoprothese nach Anspruch 10, wobei:

im Wesentlichen alle der Poren jedes länglichen Elements zur Außenfläche des länglichen Elements offen sind.

12. Endoprothese nach Anspruch 10, wobei:

die Außenfläche jedes der länglichen Elemente einen Gesamtaußenflächeninhalt aufweist, der einen Porenflächeninhalt umfasst, der aus den vereinten Flächeninhalten der Poren besteht, die zur Außenfläche offen sind; und

der Gesamtporenflächeninhalt von etwa zwei Prozent bis etwa vierzig Prozent des Gesamtaußenflächeninhalts reicht.

13. Endoprothese nach Anspruch 8, wobei:

die Poren Durchmesser aufweisen, die von etwa 1 Mikrometer bis etwa 20 Mikrometer reichen.

14. Endoprothese nach Anspruch 1, wobei:

das Volumen jedes Reservoirabschnitts von zwanzig Prozent bis etwa vierzig Prozent seines zugehörigen Gesamtvolumens reicht.

15. Endoprothese nach Anspruch 14, wobei:

die länglichen Elemente an den mehreren Kreuzungen Kreuzungswinkel bilden, die von etwa 120 Grad bis etwa 150 Grad reichen.

16. Endoprothese nach Anspruch 1, wobei:

das biologisch abbaubare Polymer im Wesentlichen aus einem Polymer besteht, das aus der Gruppe bestehend aus PLLA, PDLA und ihren Kombinationen ausgewählt ist.

17. Endoprothese nach Anspruch 1, wobei:

das biologisch abbaubare Polymer im Wesentlichen aus einem Polymer besteht, das aus der Gruppe bestehend aus Polylactid, Polyglycolid und ihren Kombinationen ausgewählt ist.

18. Endoprothese nach Anspruch 1, wobei:

das biologisch abbaubare Polymer aus einem Polymer besteht, das aus der Gruppe bestehend aus Polyglycolid, Polygluconat, Polydioxanon und ihren Kombinationen ausgewählt ist.

19. Endoprothese nach Anspruch 1, wobei:

jedes der länglichen Elemente im Wesentlichen aus dem biologisch abbaubaren Polymer besteht.

20. Endoprothese nach Anspruch 1, wobei:

die länglichen Elemente elastisch sind, wodurch die Röhrenstruktur dazu neigt, einen freien Zustand anzunehmen, in welchem die Röhrenstruktur einen ersten Durchmesser aufweist und, wenn radial in den Zustand mit verkleinertem Radius und erweiterter Länge zusammengedrückt, einen zweiten Durchmesser aufweist, der kleiner als der erste Durchmesser ist.

21. Verfahren zur Herstellung einer in den Körper implantierbaren Endoprothese, die erste und zweite Sätze von elastischen länglichen Elementen umfasst, umfassend:

Bereitstellen einer Röhrenstruktur (50), umfassend einen ersten Satz von länglichen Elementen (20, 30, 40), die sich in einer spiralförmigen Anordnung in einer ersten Wickelrichtung entlang einer Mittellinie der Röhrenstruktur erstrecken, und einen zweiten Satz von länglichen Elementen (20, 30, 40), die sich in einer spiralförmigen Anordnung in einer zweiten Wickelrichtung entlang der Mittellinie erstrecken und mit dem ersten Satz von länglichen Elementen kreuzen, um Kreuzungen der länglichen Elemente und Zwischenräume zwischen den länglichen Elementen zu bilden; wobei die Röhrenstruktur in einen Zustand mit verkleinertem Radius und erweiterter Länge zusammendrückbar ist, und wobei jedes der länglichen Elemente ein biologisch abbaubares Polymer umfasst, das so ausgelegt ist, dass es eine in-vivo-Zersetzung erfährt, und ferner einen Reservoirabschnitt umfasst, der so ausgelegt ist, dass er ein Nebenprodukt der Zersetzung des biologisch abbaubaren Polymers sammelt, wobei der Reservoirabschnitt ein Reservoirvolumen einnimmt, das größer als etwa fünf Prozent eines Gesamtvolumens des länglichen Elements ist, das durch das längliche Element eingenommen wird;

Anordnen der Röhrenstruktur auf einem Dorn und, mit der Röhrenstruktur auf dem Dorn angeordnet, Tempern der Röhrenstruktur bei einer Temperatur, die niedriger als der Schmelzpunkt des biologisch abbaubaren Polymers ist, für eine Zeit von 5 Minuten bis 20 Minuten; und
Abkühlen der Röhrenstruktur nach dem Tempern und anschließendes Entfernen der Röhrenstruktur vom Dorn.

22. Verfahren nach Anspruch 21, wobei:

das Bereitstellen der Röhrenstruktur ein Bilden der jeweiligen Reservoirabschnitte in den länglichen Elementen umfasst.

23. Verfahren nach Anspruch 22, wobei:

das Bilden der jeweiligen Reservoirabschnitte ein Extrudieren der länglichen Elemente derart, dass die jeweiligen Reservoirabschnitte bereitgestellt werden, umfasst.

24. Verfahren nach Anspruch 22, wobei:

das Bilden der Reservoirabschnitte ein Entkernen der länglichen Elemente während eines Spritzgießens davon umfasst.

25. Verfahren nach Anspruch 22, wobei:

das Bilden der Reservoirabschnitte ein Einarbeiten von lösbaren Mikrokügelchen in die länglichen Elemente umfasst.

26. Verfahren nach Anspruch 22, wobei:

das Bilden der Reservoirabschnitte ein Bohren von axialen Löchern in den länglichen Elementen umfasst.

27. Verfahren nach Anspruch 26, wobei:

das Bereitstellen der Reservoirabschnitte ferner ein Versiegeln von jeweiligen offenen Enden der axialen Löcher in den länglichen Elementen umfasst.

28. Verfahren nach Anspruch 21, ferner umfassend:

Zuschneiden der Röhrenstruktur auf vorbestimmte axiale Längen nach dem Entfernen der Röhrenstruktur vom Dorn.

29. Verfahren nach Anspruch 21, wobei:

das Tempern ein Erwärmen der Röhrenstruktur auf eine Temperatur innerhalb des Bereichs von etwa 20 Grad Celsius bis etwa 160 Grad Celsius für eine Zeit innerhalb eines Bereichs von etwa zehn Minuten bis etwa zwanzig Minuten umfasst.

30. Verfahren nach Anspruch 21, wobei:

das Bereitstellen der Röhrenstruktur ein Flechten der länglichen Elemente auf einem Flechtdorn umfasst, um einen Vortemperdurchmesser der Röhrenstruktur festzulegen, wenn in einem freien Zustand.

31. Verfahren nach Anspruch 30, wobei:

das Tempern ein Halten der Röhrenstruktur im freien Zustand auf dem Temperdorn umfasst.

32. Verfahren nach Anspruch 30, wobei:

das Tempern ein Halten der Röhrenstruktur in einem axial erweiterten Zustand auf dem Temperdorn umfasst.

33. Verfahren nach Anspruch 30, wobei:

das Tempern ein Halten der Röhrenstruktur in einem axial zusammengedrückten Zustand auf dem Temperdorn umfasst.

Revendications

1. Endoprothèse implantable bioabsorbable comportant :

une structure tubulaire tressée compressible radialement, auto expansible et recuite (50) comprenant un premier ensemble d'éléments allongés (20, 30, 40) s'étendant en forme hélicoïdale dans un premier sens d'enroulement le long d'une ligne centrale de la structure tubulaire et un deuxième ensemble d'éléments allongés (20, 30, 40) s'étendant en forme hélicoïdale dans un deuxième sens d'enroulement le long de la ligne centrale de la structure tubulaire et croisant le premier ensemble d'éléments allongés pour former des intersections des éléments allongés et des interstices entre les éléments allongés ;

dans laquelle chacun des éléments allongés contient un polymère bioabsorbable apte à subir une dégradation *in vivo* ; et
dans laquelle les éléments allongés sont résilients afin de permettre une compression radiale de la structure tubulaire jusqu'à un état à rayon réduit et longueur étendue afin de faciliter une délivrance trans-lumen de la structure tubulaire vers un site de traitement sélectionné,
caractérisée en ce que chacun desdits éléments allongés comprend en outre un segment de réservoir apte à collecter un produit secondaire de la dégradation du polymère bioabsorbable, le segment de réservoir occupant un volume de réservoir supérieur à environ cinq pour cent d'un volume total occupé par l'élément allongé.

2. Endoprothèse selon la revendication 1, dans laquelle :

le segment de réservoir comprend un segment creux s'étendant axialement le long de chacun des éléments allongés et ouvert sur les extrémités opposées de chaque élément.

3. Endoprothèse selon la revendication 2, dans laquelle :

le segment de réservoir comprend une pluralité desdits segments creux.

4. Endoprothèse selon la revendication 2, dans laquelle :

une surface moyenne de section transversale du segment creux comprend d'environ dix pour cent à environ 30 pour cent de la surface totale de section transversale de l'élément allongé.

5. Endoprothèse selon la revendication 1, dans laquelle :

le segment de réservoir comprend au moins une cavité interne s'étendant axialement en retrait de la surface extérieure de chacun des éléments allongés.

6. Endoprothèse selon la revendication 5, dans laquelle :

l'au moins une cavité a une surface moyenne de section transversale comprise entre environ deux pour cent et environ 40 pour cent de la surface totale de section transversale de l'élément allongé.

7. Endoprothèse selon la revendication 5, dans laquelle :

une surface moyenne de section transversale de la cavité est comprise entre environ dix pour cent et environ 30 pour cent de la surface de section transversale de son élément allongé associé.

8. Endoprothèse selon la revendication 1, dans laquelle :

le segment de réservoir comprend une pluralité de pores.

9. Endoprothèse selon la revendication 8, dans laquelle :

les pores sont en retrait d'une surface extérieure de chacun des éléments allongés.

10. Endoprothèse selon la revendication 8, dans laquelle :

au moins certains des pores de chaque élément allongé sont ouverts sur une surface extérieure de l'élément allongé.

11. Endoprothèse selon la revendication 10, dans laquelle :

sensiblement tous les pores de chaque élément allongé sont ouverts sur une surface extérieure de l'élément allongé.

12. Endoprothèse selon la revendication 10, dans laquelle :

la surface extérieure de chacun des éléments allongés a une zone totale de surface extérieure incluant une zone de surface de pores composée des zones de surface combinées des pores ouverts sur la surface extérieure ; et
la zone totale de surface de pores est comprise entre environ deux pour cent et environ quarante pour cent de la zone totale de surface extérieure.

13. Endoprothèse selon la revendication 8, dans laquelle :

les pores ont des diamètres compris entre environ 1 micron et environ 20 microns.

14. Endoprothèse selon la revendication 1, dans laquelle :

le volume de chaque segment de réservoir est compris entre vingt pour cent et environ quarante pour cent de son volume total associé.

15. Endoprothèse selon la revendication 14, dans laquelle :

les éléments allongés, aux intersections multiples, forment des angles de croisement compris entre environ 120 degrés et environ 150 degrés.

16. Endoprothèse selon la revendication 1, dans laquelle :

le polymère bioabsorbable est composé substantiellement d'un polymère sélectionné parmi le groupe composé de : PLLA, PDLA et leurs combinaisons.

17. Endoprothèse selon la revendication 1, dans laquelle :

le polymère bioabsorbable est composé substantiellement d'un polymère sélectionné parmi le groupe composé de : polylactide, polyglycolide et leurs combinaisons.

18. Endoprothèse selon la revendication 1, dans laquelle :

le polymère bioabsorbable est composé substantiellement d'un polymère sélectionné parmi le groupe composé de : polyglycolide, polygluconate, polydioxanone et leurs combinaisons.

19. Endoprothèse selon la revendication 1, dans laquelle :

chacun des éléments allongés est composé substantiellement de polymère bioabsorbable.

20. Endoprothèse selon la revendication 1, dans laquelle :

les éléments allongés sont résilients, ce qui a pour effet que la structure tubulaire a tendance à prendre un état

libre dans lequel la structure tubulaire a un premier diamètre et, lorsqu'elle est compressée radialement jusqu'à l'état à rayon réduit et longueur étendue, a un deuxième diamètre inférieur au premier diamètre.

21. Processus de fabrication d'une endoprothèse implantable dans le corps comprenant un premier et un deuxième ensemble d'éléments allongés résilients, englobant :

la création d'une structure tubulaire (50) comprenant un premier ensemble d'éléments allongés (20, 30, 40) s'étendant en forme hélicoïdale dans un premier sens d'enroulement le long d'une ligne centrale de la structure tubulaire et un deuxième ensemble d'éléments allongés (20, 30, 40) s'étendant en forme hélicoïdale dans un deuxième sens d'enroulement et croisant le premier ensemble d'éléments allongés pour former des intersections des éléments allongés et des interstices entre les éléments allongés, la structure tubulaire étant compressible radialement jusqu'à un état à rayon réduit et longueur étendue et chacun des éléments allongés contenant un polymère bioabsorbable apte à subir une dégradation *in vivo* et comprenant en outre un segment de réservoir apte à collecter un produit secondaire de la dégradation du polymère bioabsorbable, le segment de réservoir occupant un volume de réservoir supérieur à environ cinq pour cent d'un volume total d'élément allongé occupé par l'élément allongé ;
la disposition de la structure tubulaire sur un mandrin et, la structure tubulaire étant disposée sur le mandrin, le recuit de la structure tubulaire à une température inférieure au point de fusion du polymère bioabsorbable pendant une durée allant de 5 minutes à 120 minutes ; et
après recuit, le refroidissement de la structure tubulaire puis l'enlèvement de la structure tubulaire du mandrin.

22. Processus selon la revendication 21, dans lequel :

ladite création d'une structure tubulaire comprend le formage des segments de réservoir respectifs dans les éléments allongés.

23. Processus selon la revendication 22, dans lequel :

ledit formage des segments de réservoir inclut l'extrusion des éléments allongés de manière à créer les segments de réservoir respectifs.

24. Processus,selon la revendication 22, dans lequel :

ledit formage des segments de réservoir inclut le carottage des éléments allongés pendant leur moulage par injection.

25. Processus selon la revendication 22, dans lequel :

ledit formage des segments de réservoir inclut l'incorporation de microsphères solubles dans les éléments allongés.

26. Processus selon la revendication 22, dans lequel :

ledit formage des segments de réservoir inclut le forage de trous axiaux dans les éléments allongés..

27. Processus selon la revendication 26, dans lequel :

ladite création des segments de réservoir inclut en outre le scellement des extrémités ouvertes respectives des trous axiaux pratiqués dans les éléments allongés.

28. Processus selon la revendication 21, comprenant en outre :

après l'enlèvement de la structure tubulaire du mandrin, la découpe de la structure tubulaire en longueurs axiales prédéterminées.

29. Processus selon la revendication 21, dans lequel :

ledit recuit comprend le chauffage de la structure tubulaire à une température se situant dans une plage d'environ

130 degrés C à environ 160 degrés C pendant une durée se situant dans une plage d'environ dix minutes à environ vingt minutes.

30. Processus selon la revendication 21, dans lequel :

ladite création de la structure tubulaire comprend le tressage des éléments allongés sur un mandrin de tressage afin de déterminer un diamètre de pré-recuit de la structure tubulaire lorsqu'elle est à l'état libre.

31. Processus selon la revendication 30, dans lequel :

ledit recuit comprend le maintien de la structure tubulaire à l'état libre sur le mandrin de recuit.

32. Processus selon la revendication 30, dans lequel :

ledit recuit comprend le maintien de la structure tubulaire en état étendu axialement sur le mandrin de recuit.

33. Processus selon la revendication 30, dans lequel :

ledit recuit comprend le maintien de la structure tubulaire en état compressé axialement sur le mandrin de recuit.

FIG. 1

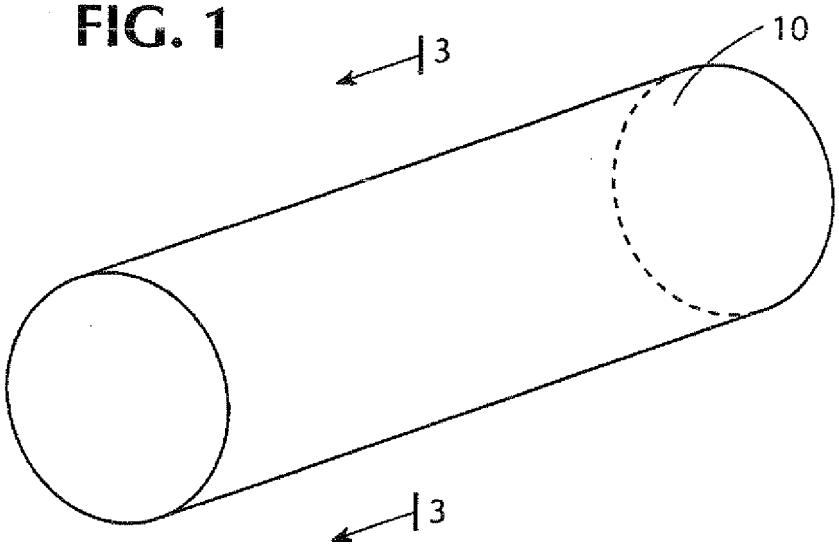


FIG. 2a

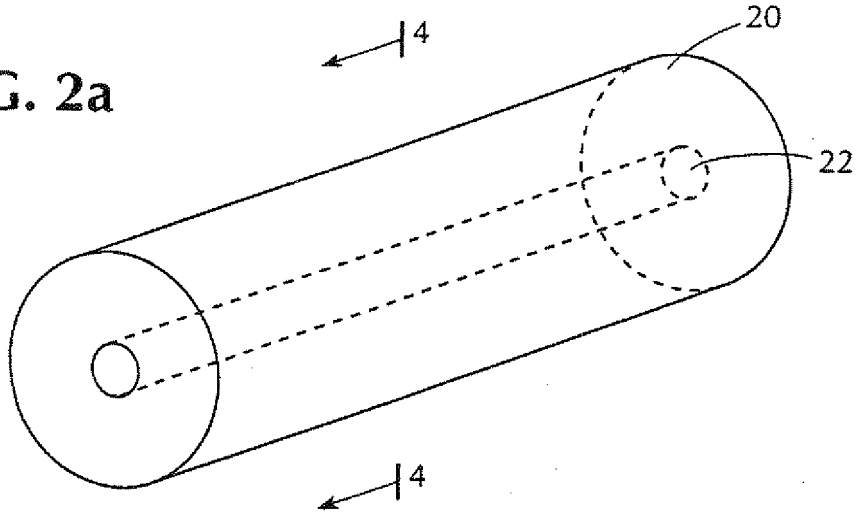


FIG. 2b

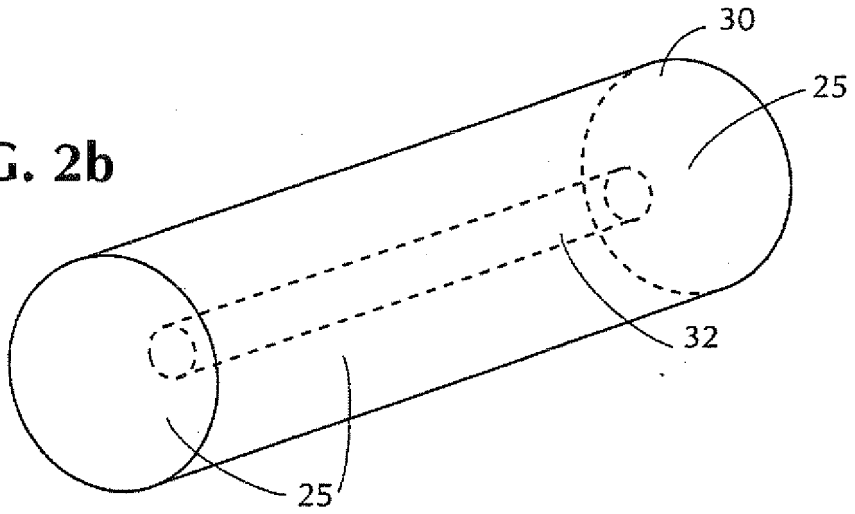


FIG. 2c

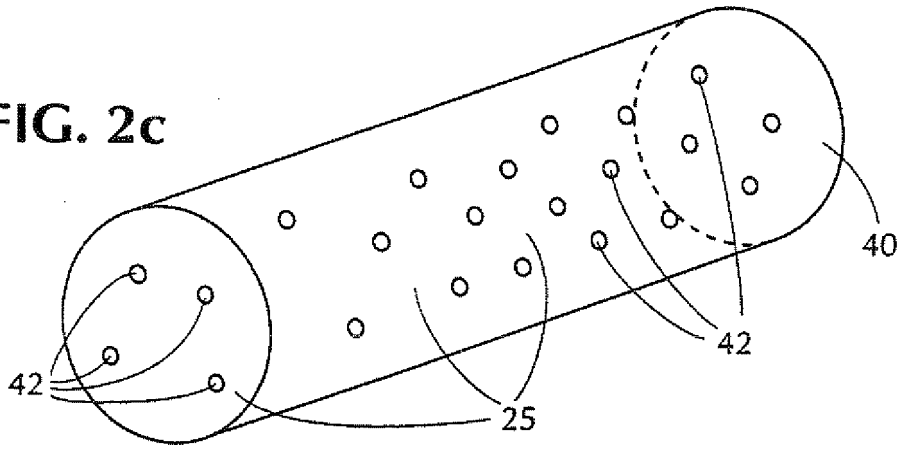


FIG. 2d

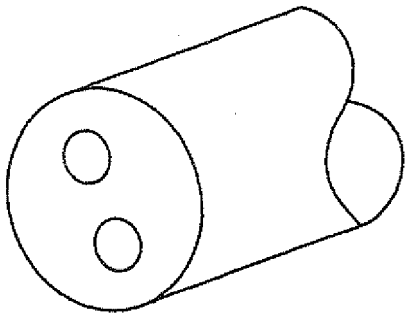


FIG. 2e

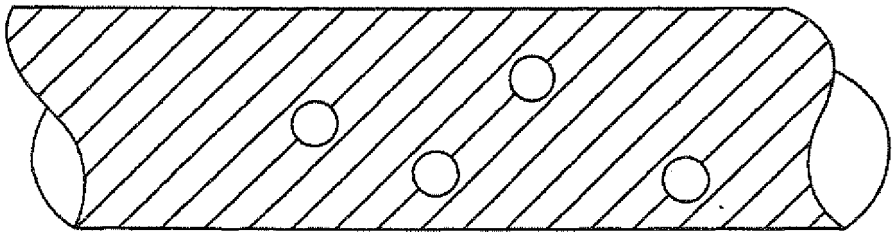


FIG. 2f

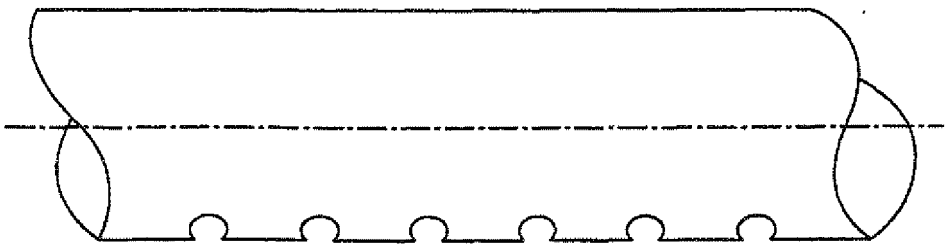


FIG. 3a

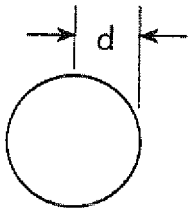


FIG. 3b

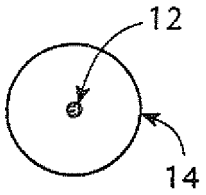


FIG. 3c

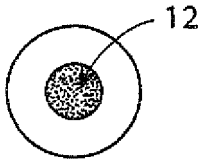


FIG. 3d

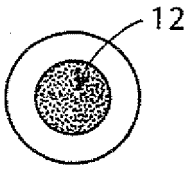


FIG. 3e

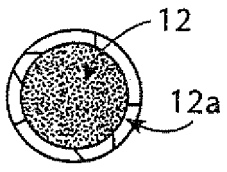


FIG. 3f

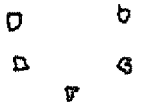


FIG. 4a

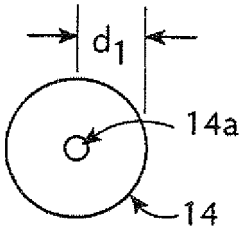


FIG. 4b

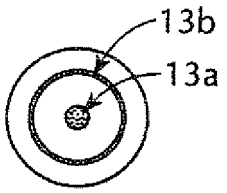


FIG. 4c

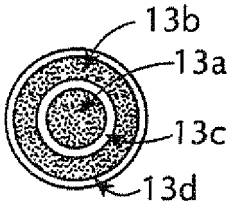


FIG. 4d

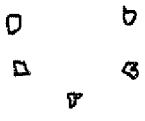


FIG. 5

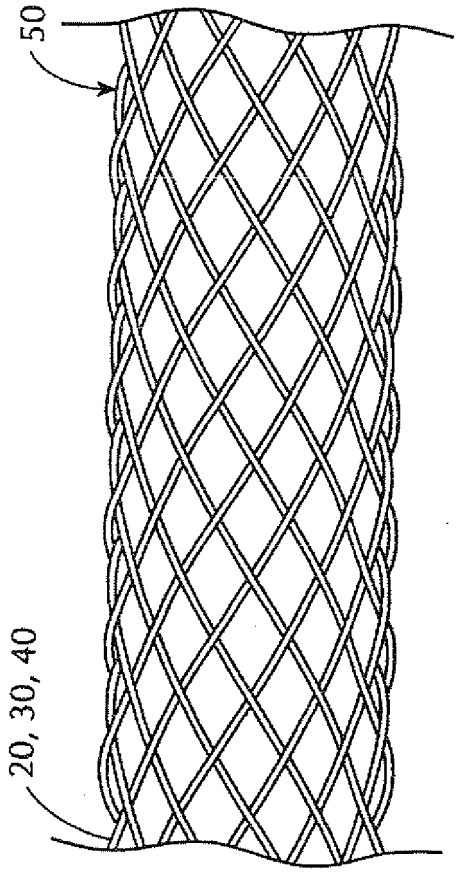
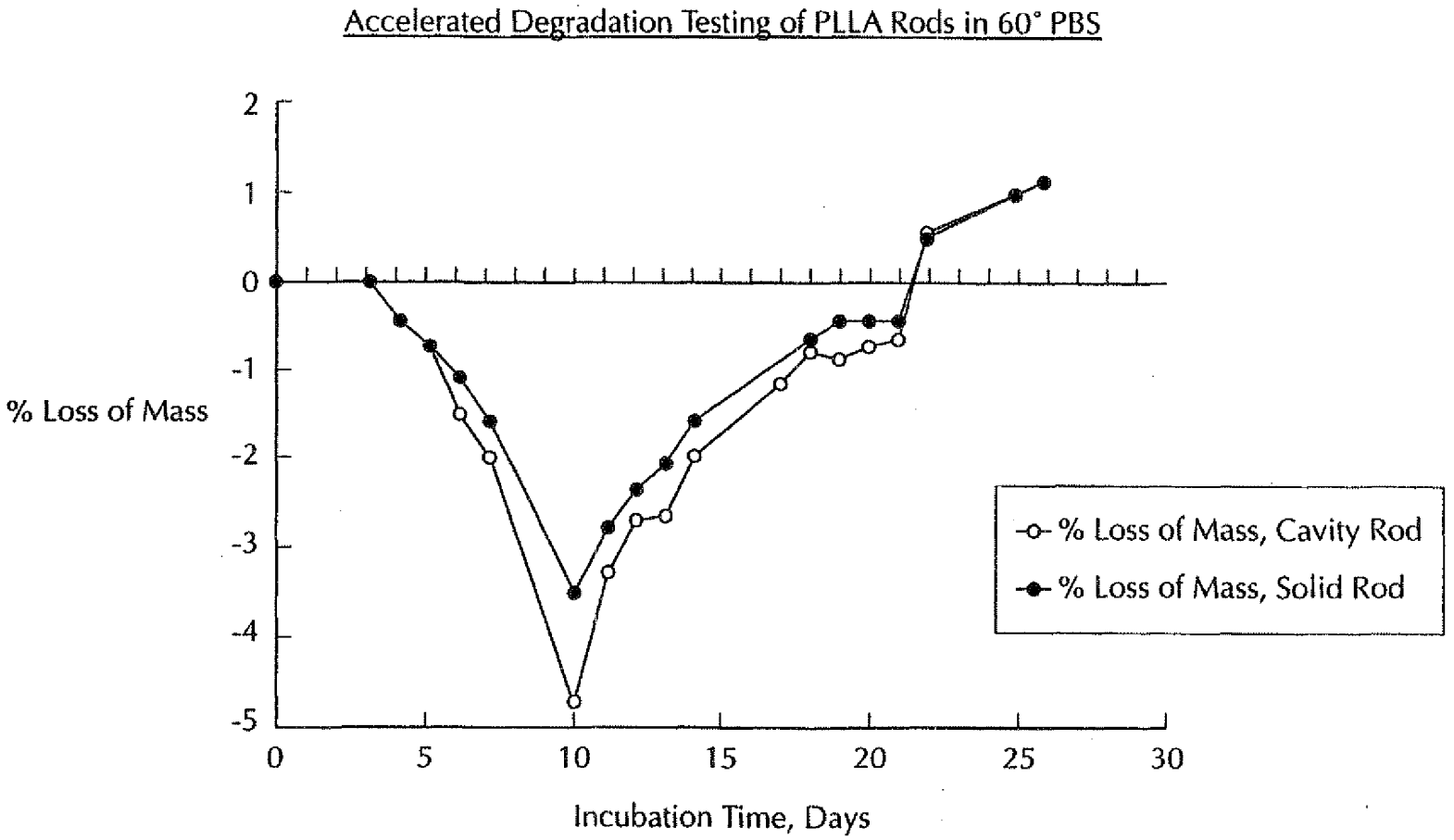


FIG. 6



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REFERENCES CITED IN THE DESCRIPTION

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Patent documents cited in the description

- US 4655771 A, Wallsten **[0002] [0045]**
- US 5061275 A, Wallsten **[0002] [0045]**
- US 5645559 A, Hachtmann **[0002]**
- US 5500013 A **[0003]**
- US 4954126 A **[0005]**
- US 5026377 A **[0005]**
- US 6042578 A **[0005]**
- US 5630840 A, Mayer **[0006]**
- US 5888201 A **[0006]**
- WO 9117789 A **[0011]**
- US 6245103 B **[0088]**
- US 08904467 B **[0088]**
- US 6340367 B **[0089]**
- US 08905821 B **[0089]**
- US 6174330 B **[0090]**
- US 08904951 B **[0090]**

Non-patent literature cited in the description

- **W. WEILER ; S. GOGOLEWSKI.** *Biomaterials,* 1996, vol. 17 (5), 529-535 **[0026]**
- **C. MAULI ; AGRAWAL, PH.D., P.E. ; H. G. CLARK, PH.D.** *Deformation Characteristics of a Bioabsorbable Intravascular Stent, Investigative Radiology,* December 1992, 1020-1024 **[0026]**